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COMMENT ON WAYS TO MANAGE QUALIFIED HEALTH CLAIMS

2003N-0496 - Food and Dietary Supplement Labeling: Health Claims; Dietary Guidance

As a researcher on risk analysis and communication, I appreciate the opportunity to comment on FDA's proposed rulemaking on evaluating qualified health claims. Though these comments are directed at dietary supplement labeling, they can be generalized to a wide range of communication issues facing FDA. The goal of product labeling should be to help consumers make informed *purchase* decisions and, in cases where they decide to take the product, further make informed choices when using the product. It is, therefore a form of risk communication. As such, it is essential that the information is valid, characterizes uncertainty and is relevant to the decision.

Of the three alternatives proposed by FDA in this Advanced Notice, the preferred alternative for regulating qualified health claims (as well as other aspects of dietary supplement labeling) is a combination of FDA proposed alternatives 1 and 2—a **premarket clearance system** that "provides for (a) FDA review of qualified claims and the supporting data, and (b) a measure of public participation," that also "**reinterprets the [significant scientific agreement] (SSA) standard to apply to the claim** (including the disclaimer, if any) instead of the underlying substance-disease relationship, so that the agency would focus on whether the words of the claim accurately reflect the data supporting it (e.g., "limited and preliminary scientific research suggest . . .") [and would be

interpreted in that way by both typical consumers and ones most vulnerable if they misunderstand the label] rather than whether there is SSA supporting the substance-disease relationship."

However, we believe the following issues—burden of proof, standard reporting, public participation and consumer testing—should be considered when making final regulations. Each is discussed further below.

Burden of proof (scientific validity and consumer processing) Adequate risk communication must reflect (a) the physical reality of products' effects and (b) the behavioral reality of consumers' information processing. There are many advantages of shifting the burden of proof from FDA, to show that a claim is inherently or potentially misleading, to the manufacturer to show that a claim informs consumers in a manner relevant to their decision making. It would alleviate FDA's burden of compiling research over the entire spectrum of supplements, spreading costs and paperwork out among the manufacturers. As such, it would create incentives for cost-effective research, focusing on the most salient aspects of the claims. Over time, having a standard research protocol will lead to better understanding of consumer process of health information and the efficient development of communications. If widely and consistently applied, a communication standard might gradually educate consumers, expanding their range of effective decision making (as FDA's nutrition label may have done). Having better informed consumers would make it easier to bring new products to market.

For this to work, FDA must first set priorities on product safety and efficacy as well as consumer understanding and decision making. It should then redefine the standard of "significant scientific agreement" in terms of its adequacy for informing consumer decision making. That standard should be operationalized in consumer testing protocols and standard reporting formats. Manufacturers would then be required to demonstrate the validity of the claim, in terms of whether it reflects sufficient scientific agreement to serve the predicted consumer decision-making processes.

Standard reporting. Out of the Nutrition Labeling Education Act came the Daily Recommended Value and Nutrition Facts Panel found on packaged foods. These standard formats provide consistent and relevant information that 1) validates other health-related statements appearing on

the label and 2) informs consumers about the recommended intake amounts for given nutrients. The difference for dietary supplements is that there is often no validating information. For example, if a claim is made that calcium is necessary to prevent osteoporosis, one can look to see that FDA has set a daily recommended value for calcium. This is not the case for many dietary supplements for which no daily recommended value has been established. Standard reporting for dietary supplement labels may help consumers sort out confusing information about dietary supplements found elsewhere (e.g. other advertisements). This reporting may look more like that for over-the-counter prescription drugs than the Nutrition Facts Panel. The behaviorally informed research of Woloshin and Schwartz, at Dartmouth, offers a promising direction for such labels.

Public Participation/Consumer testing. The public should be involved in at least two steps of the regulatory process. The first is when setting standards for evaluation, such as establishing SSA, or determining the priorities between product risks and benefits. Allowing for public comment is one way, but perhaps more useful public participation would come out of community discussion, such as structured interviews or surveys.

The public should also be involved in the evaluation phase. Regulating labeling, as well as the safety and efficacy of dietary supplements, requires assumptions about consumers' ability to process information and make choices in the consumer's best interest. These may reflect agency philosophy or be assessed empirically, usually a combination of both. In July 2003, FDA's Task Force on Consumer Health Information for Better Nutrition unveiled a consumer research program (http://www.cfsan.fda.gov/~dms/nuttf-d.html). The goals of this study are to "determine whether health claims that do not meet the 'SSA standard of evidence'-level of scientific support are misleading to consumers and to evaluate options for generic disclaimers to correct misleading perceptions. The study compares perceptions about the validity and meaning of claims of subjects given varying amounts of information (including some given "full" information about the diet-disease relationship).

Examining perceptions is a necessary step, but this study currently misses the decision making component, that is, how do people's perceptions, along with their values, influence their decisions? And are these decisions optimal? To answer these questions, FDA must generate data on the characteristics of the consumer population (e.g. being at risk for health condition that may be

exacerbated by taking the dietary supplement; how they value a particular health condition). They should also investigate how judgments about health claims affect decisions. For example, in the current research design, subjects are shown a label with different health statements and asked:

> "How much of a health benefit, if any, would eating this ¬food product| as a regular part of one's diet have on preventing a person from ¬getting (having) disease (health condition)|? On a scale from 1 to 10, where 1 is 'no benefit at all' and 10 is 'a large benefit'."

A useful follow-up question may address the subject's intentions to buy or use the product, given this information.

In conclusion, FDA is moving in a direction of behaviorally informed regulation by including consumer understanding in the evaluation of qualified health claims. To further its efforts, FDA should consider setting standards based on the adequacy of consumer decision making and incorporate a standard reporting format, such as is found on the Nutrition Facts Panels and over-the-counter drug labeling. Finally, FDA should move toward regulation based on public participation and empirical testing of consumer decision making.

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